

Off-Label Drug Use

Table of Content

[Purpose](#)
[Description & Definitions](#)
[Criteria](#)
[Coding](#)
[Document History](#)
[References](#)
[Special Notes](#)
[Keywords](#)

Effective Date	10/2008
Next Review Date	10/2024
Coverage Policy	Pharmacy 12
Version	4

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details*.

Purpose:

This policy addresses the medical necessity of Off-Label Drug Use.

Description & Definitions:

Off-Label drug use describes using medication that is approved by the Food and Drug Administration for something that is otherwise not intended per the drug label and/or drug insert.

Criteria:

Off-label drug use and off-label dosing are considered medically necessary for **All** of the following:

- Sentara Health Plan Pharmacist or Sentara Health Plan Medical Director approval obtained
- The drug is currently approved by the United States Food and Drug Administration (FDA) for another indication
- The drug is being prescribed to treat a medical condition that is not listed in the product's label and for which medical treatment is medically necessary
- The prescribed drug use or dosing regimen is supported by **1 of more** of the following:
 - American Hospital Formulary Service Drug Information® (AHFS®)
 - American Society of Health-System Pharmacists Drug Information [AHFS Drug Information]
 - Micromedex DrugDex System [DrugDex]
 - Clinical Pharmacology (Elsevier/Gold Standard, Inc.)
 - Lexi-Drugs (Wolters Kluwer)
 - Truven Health Analytics Inc., DrugPoints® with **all of the** following:
 - Strength of Recommendation Class I or IIa
 - Strength of Evidence Category A or B
 - Efficacy Class I or IIa
 - National Comprehensive Cancer Network® (NCCN®) Drug & Biologics Compendium® Category of Evidence and Consensus 1 or 2A
 - Two articles from major scientific or medical peer-reviewed journals (excluding case reports, letters, posters, and abstracts), or published studies having validated and uncontested data, which support

- the proposed use for the specific medical condition as safe and effective using **1 or more** of the following:
 - Examples of accepted journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet.
 - Accepted study designs include, but are not limited to, randomized, double blind, placebo controlled clinical trials.

Off-label drug use is considered **not medically necessary** for any use other than those indicated in clinical criteria.

Coding:

Medically necessary with criteria:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2020: December
- 2019: November
- 2014: November
- 2013: October
- 2012: November
- 2011: March

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- 2023: October
- 2022: October
- 2021: December
- 2019: February
- 2018: February
- 2017: January
- 2015: September
- 2010: December
- 2009: November

Effective Date:

- November 2008

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

"Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices. (2020, May 6). Retrieved Sept 21, 2023, from FDA: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices>

(2023). Retrieved Sept 22, 2023, from HAYES:
<https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Off-Label%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522sources%2522:%255B%2>

(2023). Retrieved Sept 2023, from MCG 27th Edition: <https://careweb.careguidelines.com/ed27/index.html>

(2023). Retrieved Sept 22, 2023, from CMS: <https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=Off-Label&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all>

(2023, Aug 4). Retrieved Sept 2023, from DMAS: <https://www.dmas.virginia.gov/searchblox?query=off-label&col=1&page=1&pagesize=10&sort=relevance&sortdir=desc&default=AND&f.conenttype.size=10&f.colname.size=10&f.keywords.size=10&facet.field=contenttype&facet.field=keywords&public=true&tune=true&tune.0=5>

NCCN Recognition Program. (2023). Retrieved Sept 22, 2023, from National Comprehensive Cancer Network: <https://www.nccn.org/compendia-templates/compendia/recognition-program>

Off-Label Medication: From a Simple Concept to Complex Practical Aspects. (2021, Oct). Retrieved Sept 21, 2023, from International Journal Environmental Research and Public Health: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8508135/>

Off-Label Use of Prescription Drugs. (2021, Feb 23). Retrieved Sep 21, 2023, from Congressional Research Service: <https://sgp.fas.org/crs/misc/R45792.pdf>

Special Notes: *

This medical policy expresses Sentara Health Plan's determination of medical necessity of services, and they are based upon a review of currently available clinical information. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Keywords:

SHP Off-Label Drug Use, SHP Pharmacy 12, Food and Drug Administration, FDA